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**March 29, 2004**

AstraZeneca's **Faslodex** meets unmet need in breast cancer.

**Faslodex ( fulvestrant)**, the first new estrogen receptor antagonist since tamoxifen, has finally been launched by **AstraZeneca** in Europe, two years after it has been available in the USA and South America. The product, which boasts a unique mode of action, is now available in Germany, Sweden and Austria and will be rolled out over the next year across the whole of the European Union, including the EU accession countries, Iceland and Norway.

The drug acts by binding to estrogen receptors in breast cancer cells and degrading them. It therefore puts a stop to tumor estrogen receptor activity, preventing transcription occurring that promotes cell growth. Unlike aromatase inhibitors, which prevent the synthesis of estradiol in other body tissues by blocking the aromatase enzyme, **Faslodex** does not reduce the normal amount of circulating estradiol needed to help keep a normal lipid profile and healthy cardiovascular system, prevent vaginal symptoms, maintain bone mineral density and protect cognitive function.

**Faslodex** is now licensed for post-menopausal women with estrogen receptor-positive locally-advanced or metastatic breast cancer who have experienced disease progression on or after anti-estrogen therapy. There has been an unmet need for an effective endocrine therapy which works in women who have become resistant to other hormonal treatments including tamoxifen and aromatase inhibitors. The potential population for this in Europe is around 120,000 women.

US medical oncologist John Pippin of Baylor Sammons Cancer Center, Dallas, said the availability of **Faslodex** for a similar indication in the USA has led to rapid uptake among thousands of women. Usually the next step would be cytotoxic chemotherapy treatment but **Faslodex** offers another strategy to delay this move and so has proved highly popular. There is no cross-resistance between this drug and other hormonal treatments, he said.

Sales so far "beyond expectations"

Uptake has been "beyond expectation," says the company. Global brand director Sarah Holland says **Faslodex** has been AstraZeneca's most successful hormonal cancer treatment at launch in the USA, reaching annual sales of \$75 million by its second year.

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Speaking at the European launch during the 4th European Breast Cancer Conference in Hamburg, Germany, John Robertson, head of Nottingham University's breast cancer unit in the UK, said the new drug, administered as a once-monthly injection, improves on tamoxifen because, while it also blocks estrogen uptake by breast tumors it does not have tamoxifen's partial estrogenic activity.

The latter is implicated in tamoxifen complications such as endometrial cancer, venous thrombo-embolism and stimulation of tumor cells once estrogen receptors start to show resistance following around five years' therapy. **Faslodex** is a better tolerated treatment than tamoxifen and aromatase inhibitors, causing fewer troublesome side effects in the way of hot flushes, joint disorders and vaginal symptoms.

Kurt Possinger, chairman of the Department of Oncology and Hematology, Huboldt University, Berlin, Germany, said **Faslodex** is supported by two large trials comparing it against tamoxifen and aromatase inhibitors. The drug is able to shrink breast tumors more than 50%. Compared against the aromatase inhibitor Arimidex (anastrozole), also an AstraZeneca drug (see page 20), it has a significantly longer duration of response. Prof Possinger already believes it is a better treatment than other endocrine therapies and could be used in preference to aromatase inhibitors after tamoxifen or, eventually, even before tamoxifen. "In my eyes it's the first-line therapy," he concluded.

---- INDEX REFERENCES ---

COMPANY: ASTRAZENECA; ASTRAZENECA LTD; ASTRAZENECA SA; ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA (NETHERLANDS ANTILLES); ASTRAZENECA (LATVIA); APTIUM ONCOLOGY; ASTRAZENECA (NICARAGUA); ASTRAZENECA PLC

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